K093772

SYNTHES®

MAR 29 2010

3.0 510(k) Summary

Sponsor:
Synthes
1301 Goshen Parkway
West Chester, PA 19380

Contact:
Contact: Andrea M. Tasker
tasker.andrea@synthes.com
(610) 719-6290

Device Name:
Synthes Sternal Fixation System—Modification to Surgical Technique

Classification:
888.3030 – Plate, Fixation, Bone, Non-Spinal, Metallic (HRS)
888.3040 – Screw, Fixation, Bone, Non-Spinal, Metallic (HWC)

Predicate Devices:
Synthes Sternal Fixation System
Synthes Sterile Sternal Fixation System
Ethicon Stainless Steel Suture Wire

Device Description:
The Synthes (USA) Sternal Fixation System consists of machined titanium plates, a quick-release pin and 3.0 mm locking screws. The plates utilize screw fixation to create the construct.

Intended Use:
The Synthes Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

The Synthes (USA) Titanium 2.4 mm Universal Locking Plates (12, 13 and 20 hole) are indicated for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Contraindications
The Synthes Titanium 2.4 mm Universal Locking Plates are contraindicated for use in acute cardiac patients.

Substantial Equivalence:
Documentation provided in this submission demonstrates the Synthes Sternal Fixation System - Modification to Surgical Technique to be substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
% Ms. Andrea M. Tasker
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAR 29 2010

Re: K093772
Trade/Device Name: Synthes Sternal Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: February 9, 2010
Received: February 16, 2010

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K093772

Device Name: Synthes Sternal Fixation System

Indications for Use: The Synthes Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

The Synthes (USA) Titanium 2.4 mm Universal Locking Plates (12, 13 and 20 hole) are indicated for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Contraindications
The Synthes Titanium 2.4 mm Universal Locking Plates are contraindicated for use in acute cardiac patients.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093772